

REMARKS

Claims 1, 2, 4, 5, 7, 16, 17, 19, 20, 22, 23, and 25-278 were rejected under §103 based on Field (US 4,636,412) in view of Ohodaira et al. (US 4,482,585) and further in view of Allen (US 5,468,526). Claims 6 and 21 were rejected as obvious based further in view of Kong (US 6,253,936). The examiner has dropped all prior grounds of rejection and substituted Allen for Lescaut.

1. Ohodaira does not disclose fluorinated rubber that includes a reinforcement layer

Claim 1 recites: “an outer layer of fluorinated rubber composite and an inner layer made of thermoplastic polyurethane, and wherein the fluorinated rubber composite includes at least one reinforcement layer for the fluorinated rubber.”

A reinforcement layer is useful because it was found that fluorinated rubber alone is prone to forming cracks, leaks, and the like when subjected to repeated bending during ordinary use of a hydration system. Page 9 of the application explains that

This laminate may be composed of several polymeric layers including a polyamide fiber reinforcement layer for strength, several rubber layers for permeation resistance, and a thermoplastic layer to allow for thermal welding. More particularly, the multiplayer laminate/composite includes a layer of fluorinated polymer such as fluorinated rubber. This layer may include other rubber materials. A representative example of such a fluorinated rubber is Viton™ rubber available from DuPont. These fluorinated rubbers may be based on hexafluoropropylene and vinylidene fluoride. Such materials are well known as being chemically resistant. Thus, in general, the fluorinated rubber composite may be multiplayer and include a polyamide reinforcement layer sandwiched between a thermoplastic polymer layer (to allow for thermal welding) and the fluorinated rubber. As used herein, “fluorinated rubber composite” or “fluorinated rubber laminate” refers to materials that include one or more fluorinated rubber layers, but may include other layers such as the polyamide and thermoplastic polymer layers.

Ohodaira does not teach or suggest a composite or a reinforcement layer. Use of the Ohodaira layer alone, without a reinforcement layer, would lead to detrimental cracking, leaking, and the

like during normal use of a system as claimed herein. Thus, the claims distinguish from the applied references.

The examiner has previously argued in the 7/8/2010 action that "Column 4 lines 15-20 of the Ohodaira reference discloses using ethylene tetrafluoroethylene copolymer (fluorinated rubber composite) being used as outer layers implying more than one layers which can be defined as reinforcement layer."

The passage at column 4 of Ohodaira cited by the examiner reads:

The periphery of the stacked sheets is then heat-sealed to provide a container bag. If films 3 of ethylene-tetrafluoroethylene copolymer are used as the outer layers, a similar container may be prepared without requiring the liquid inlet and outlet ports 4.

However, another ethylene-tetrafluoroethylene copolymer layer would not function to reinforce another ethylene-tetrafluoroethylene copolymer layer - the combination would remain prone to cracking, leaking, and the like. Likewise, another ethylene-tetrafluoroethylene copolymer layer would not serve to add strength to the ethylene-tetrafluoroethylene copolymer layer because it is made of the same material.

The examiner's allegation is therefore incorrect and baseless. The rejection should be withdrawn at least for this reason.

2. The combination of references is improper

A. The combination of Field with Ohodaira is improper

Field discloses an outer nylon layer and an inner LLDPE layer, and the examiner proposes completely changing BOTH these layers to provide an outer fluoridated rubber layer and an inner thermoplastic polyurethane layer in Field.

Field discloses a flexible enema bag. The outer layer is Nylon. The inner layer is linear low density polyethylene (LLDPE). The primary need for this bag is that it be "water impermeable" and "flexible." (Col. 3, lines 43-46.)

In direct contrast, the Ohodaira bag is for a container resistant to extremely low temperatures. The inner layer is polyethylene having specified molecular weights and properties. The outer layer is PET (see abstract) or other like material (see col. 3, lines 40-50 where fluorinated rubber is mentioned). The mere fact that Ohodaira discloses an outer layer of fluorinated rubber does not mean that it should be used in Field.

There is likewise simply no need for materials resistant to extremely low temperatures in the enema bag of Field. There is therefore no motivation or suggestion to combine these references. The examiner has not made out a prima facie case of obviousness as to the alleged combination of Field and Ohodaira.

Furthermore, Field states that the inner and outer layers are "transparent." Field, 3:57-60. A fluorinated rubber composite is not transparent. A skilled artisan would therefore not be motivated to substitute an outer fluorinated rubber composite for an outer transparent Nylon layer of Field for to do so would defeat a required characteristic of Field.

Moreover, the examiner provides no reasoning whatsoever as to why the combination should be made. The rejection merely states a conclusion.

In view of the foregoing, the combination is improper and should be withdrawn.

Likewise, Ohodaira does not disclose a fluorinated rubber composite including at least one reinforcement layer. Therefore even if the combination is proper, the combination does not render the claims obvious.

B. The combination of Field with Allen is improper

Because neither the primary or second reference discloses an inner thermoplastic polyurethane layer, the examiner turns to Allen. The examiner asserts that

Allen discloses an apparatus that does disclose an inner layer 15 made of thermoplastic polyurethane (see fig. 1; col. 3 lines 20-25). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Field's invention by providing an outer layer made of fluorinated rubber composite as taught by Ohodaira to insure that there are no leaks formed when used in rough environment and

an inner layer made of thermoplastic polyurethane as taught by Allen so that the fluid contained in the bladder is not contaminated.

The examiner's logic is lacking and merely conclusory.

Again, Field discloses an outer nylon layer and an inner LLDPE layer, and the examiner proposes completely changing BOTH these layers to provide an outer fluoridated rubber layer and an inner thermoplastic polyurethane layer in Field.

As stated above, Field discloses a flexible enema bag. The outer layer is Nylon. The inner layer is linear low density polyethylene (LLDPE). The primary need for this bag is that it be "water impermeable" and "flexible." (Col. 3, lines 43-46.) By the examiner's logic, it would be obvious to make virtually any change to Field.

Notably, Field expressly states that the inner layer is "inert to the [barium enema] content." There is no evidence of record to suggest that a thermoplastic polyurethane layer is inert to barium enema, and the examiner provides no such evidence.

Furthermore and ironically, the claimed hydration system is designed to keep pollutants such as barium OUT of the contents, yet the examiner cites Field, which purposefully is designed to keep barium IN.

In view of the foregoing, the examiner has not made out a prima facie case of obviousness because the combination is improper.

3. Assuming the combination is proper, the combination does not render the claims obviousness

It can be seen that Field, Allen, and Ohodaira are not combinable. The examiner thus has not made out a prima facie case of obviousness. If for argument's sake the references are considered to be combinable, they do not, either alone or in combination, render the pending claims obvious because they do not add up to the claimed invention at least for the reason that the references do not disclose a rubber composite including a reinforcement layer.

Finally, Kong does not fill the deficiencies of the other references. The rejections based on Kong as a fourth reference should therefore be withdrawn for the reasons above.

Thus, it is respectfully submitted that in view of the comments above, all grounds of rejection should be withdrawn.

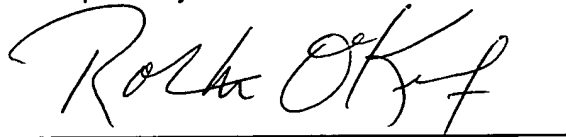
CONCLUSION

In view of the foregoing, it is submitted that the claims are in condition for allowance. Accordingly, favorable reconsideration and Notice of Allowance are courteously solicited.

Should any fees under 37 CRF 1.16-1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct such fees from Deposit Account No. 10-1205/TRIA:005. The examiner is invited to contact the undersigned at the phone number indicated below with any questions or comments, or to otherwise facilitate expeditious and compact prosecution of the application.

If the claims are allowed, applicant respectfully requests that any appropriate claims that are currently withdrawn be rejoined into the application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert O'Keefe", written over a horizontal line.

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